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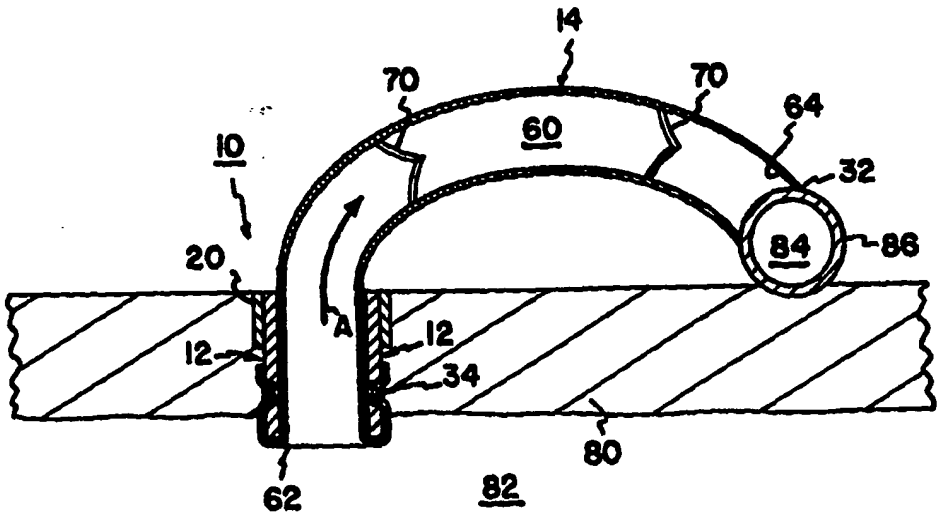
(54) Title: FLEXIBLE TRANSMYOCARDIAL IMPLANT



(57) Abstract

A transmyocardial implant includes a hollow conduit adapted to be inserted into and retained within the heart wall of a heart chamber containing oxygenated blood. The conduit is in blood–flow communication with blood contained within the chamber. A natural blood vessel graft having a first end is secured to the conduit for blood flow from the chamber to flow into the graft. The graft has a second end secured to the coronary vessel with an opening of the second end in blood flow communication with a lumen of the coronary vessel. The conduit and graft defining a blood flow path between the openings of the first and second ends.

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FLEXIBLE TRANSMYOCARDIAL IMPLANT

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to an implant for passing blood flow directly between a chamber of the heart and a coronary vessel. More particularly, this invention pertains to a flexible transmyocardial implant.

2. Description of the Prior Art

Commonly assigned and co-pending U.S. Patent Application Serial No. 08/882,397 filed June 25, 1997, entitled "Method and Apparatus for Performing Coronary Bypass Surgery", and filed in the name of inventors Mark B. Knudson and William L. Giese, teaches an implant for defining a blood flow conduit directly from a chamber of the heart to a lumen of a coronary vessel. An embodiment disclosed in the aforementioned application teaches an L-shaped implant in the form of a rigid conduit having one leg sized to be received within a lumen of a coronary artery and a second leg sized to pass through the myocardium and extend into the left ventricle of the heart. As disclosed in the above-referenced application, the conduit is rigid and remains open for blood flow to pass through the conduit during both systole and diastole. The conduit penetrates into the left ventricle in order to prevent tissue growth and occlusions over an opening of the conduit.

Commonly assigned and co-pending U.S. patent application Serial No. 08/944,313 filed October 6, 1997, entitled "Transmyocardial Implant", and filed in the name of inventors Katherine S. Tweden, Guy P. Vanney and Thomas L. Odland, teaches an implant such as that shown in the aforementioned '397 application with an enhanced fixation structure. The enhanced fixation structure includes a fabric surrounding at least a portion of the conduit to facilitate tissue growth on the exterior of the implant.

Implants such as those shown in the aforementioned applications include a portion to be placed within a coronary vessel and a portion to be placed within the myocardium. The implants disclosed in the above-mentioned applications are rigid structures. Being rigid, the implants are restricted in use. For example, an occluded

site may not be positioned on the heart in close proximity to a heart chamber containing oxygenated blood. To access such a site with a rigid, titanium implant, a very long implant must be used. A long implant results in a long pathway in which blood will be in contact with the material of the implant. With non-biological materials, such as titanium, a long residence time of blood against such materials increases the probability of thrombus. The risk can be reduced with anti-thrombotic coatings. Moreover, a rigid implant can be difficult to place while achieving desired alignment of the implant with the vessel. A flexible implant will enhance placement of the implant. Unfortunately, flexible materials tend to be non-biostable and trombogenic and may collapse due to contraction of the heart during systole.

SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, a transmyocardial implant is disclosed for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary vessel residing on an exterior of the heart. The implant includes a hollow conduit adapted to be inserted into and retained within the heart wall of a heart chamber containing oxygenated blood. The conduit is in blood-flow communication with blood contained within the chamber. A natural blood vessel graft is secured to the conduit for blood from the chamber to flow into the graft. The graft is secured to the coronary vessel in blood flow communication with a lumen of the coronary vessel. The conduit and graft define a blood flow path between the heart chamber and the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side sectional view of an implant according to the present invention; and

FIG. 2 is a side sectional view of an implant according to the present invention shown in place in a human heart wall with the implant establishing a direct blood flow path from a heart chamber to a coronary vessel.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With initial reference to FIG. 1, an implant 10 is shown including a hollow, rigid cylindrical conduit 12 and a natural tubular graft vessel 14. The conduit 12 may be formed of titanium or other rigid biocompatible material such as pyrolytic carbon or may be titanium coated with pyrolytic carbon. The material of the conduit 12 is preferably a rigid material in order to withstand contraction forces of the myocardium. While the conduit 12 is described as a solid, rigid cylinder, the conduit 12 can be any structure (e.g., an expanded stent) suitable to hold open a path through the myocardium during both systole and diastole.

The conduit 12 is sized to extend through the myocardium 80 of the human heart to project into the interior of a heart chamber 82 (preferably, the left ventricle) by a distance of about 5 mm. By way of non-limiting example, the conduit 12 will have an axial length L of about 25 - 35 mm and an outside diameter D_O of about 3 millimeters and an internal diameter D_I of about 2 millimeters to provide a wall thickness of about .5 millimeters. The conduit 12 extends from a first end 16 to a second end 18. While not shown, the second end 18 of the conduit 12 may be provided with a flange to stop insertion of the conduit 12 into the myocardium 80. Such a flange will insure penetration of the second end 16 into the left ventricle 82 and will provide a convenient location for a surgeon to suture the conduit 12 to the myocardium. Adjacent to the lower end 16, the exterior wall of the conduit 12 is provided with a circumferential groove 22, the purpose of which will be described.

As discussed more fully in the afore-mentioned commonly assigned and co-pending U.S. Patent Application Serial No. 08/944,313, the conduit 12 may be provided with tissue-growth inducing material 20 to further immobilize the conduit 12 within the myocardium 80. The material 20 is positioned adjacent upper end 18 and spaced from lower end 16 and groove 22. The material 20 surrounds the exterior of the conduit 12 and may be a polyester woven sleeve or sintered metal to define pores into which tissue growth from the myocardium 80 may occur.

The natural vessel 14 graft has first and second ends 30, 32. The first end 30 of the graft 14 is inserted through the interior of the conduit 12. The first end 30 is wrapped around the first end 16 of the conduit 12 such that the first end 30 of the

graft 14 partially covers the exterior of the conduit 12 adjacent the first end 16 of the conduit 12 and covers the groove 22. The first end 30 of the graft 14 is secured to the conduit 12 by sutures 34 tightly placed around the exterior of the graft 14 overlying the groove 22.

The conduit 12 and attached graft 14 are placed in the myocardium 80 with the first end 16 protruding into the left ventricle 82. The implant 10 thus defines an open blood flow path 60 having a first end 62 in blood flow communication with the left ventricle 82. A second end 64 of the blood flow path 60 communicates directly with the lumen 84 of the coronary vessel 86 lying on an exterior of the heart wall 80. To bypass an obstruction in a coronary artery, the end 32 of the graft 14, is anastomosed to the artery 32 with sutures (not shown) as is done in conventional coronary artery bypass procedures. The end 32 is secured to the artery 86 distal to the obstruction.

With the above-described embodiment, the implant 10 permits revascularization from the left ventricle 82 to a coronary vessel such as a coronary artery (or a coronary vein in the event of a retrograde profusion procedure). The use of an elongated, flexible graft 14 permits revascularization where the vessel 86 is not necessarily in overlying relation to the chamber 82. For example, the implant 10 permits direct blood flow between the left ventricle 82 and a vessel 86 overlying the right ventricle (not shown). The use of a natural graft 14 results in blood flowing through path 60 being exposed only to natural biological material thereby reducing risk of thrombosis. As shown in FIG. 2, the graft 14 is wrapped around the conduit 12 so that no portion of the conduit 12 is in contact with blood within the left ventricle 82.

Any suitable graft may be used. For example, the graft 14 may be an artery or vein harvested from the patient. Such harvesting is common in traditional bypass surgeries. The present invention permits harvesting a much shorter length of vessel than would be otherwise required in conventional bypass surgeries. In addition to grafts harvested from the patient, other grafts could be used. These include cryo-preserved grafts or bovine or umbilical vein glutaraldehyde treated vessels.

Certain veins, for example the saphenous vein, include natural valves 70. In the event such veins are selected as graft 14, the graft 14 is aligned so that the valves

70 are positioned to provide unobstructed flow from the left ventricle 82 to the vessel 86 as illustrated by arrow A in FIG. 2. The valves 70 act to obstruct reverse flow to the left ventricle.

Having disclosed the present invention in a preferred embodiment, it will be appreciated that modifications and equivalents may occur to one of ordinary skill in the art having the benefits of the teachings of the present invention. It is intended that such modifications shall be included within the scope of the claims which are appended hereto.

What is claimed is:

1. An apparatus for use in a coronary artery bypass procedure at a coronary vessel disposed lying on an exterior of a heart wall, the apparatus comprising;

a hollow conduit adapted to be inserted into and retained within the heart wall of a heart chamber containing oxygenated blood with the conduit in blood-flow communication with blood contained within the chamber;

a natural blood vessel graft having a first end secured to said conduit for blood flow from said chamber to flow into said graft;

said graft having a second end secured to the coronary vessel with an opening of the second end in blood flow communication with a lumen of the coronary vessel; and

the conduit and graft defining a blood flow path between the openings of the first and second ends.

2. An apparatus according to claim 1 wherein the conduit is sized to maintain a flow path through the conduit in response to cardiac contraction during systole.

3. An apparatus according to claim 1 wherein the first end of the graft is wrapped around a first end of the conduit.

4. An apparatus according to claim 1 wherein the graft has internal valves limiting flow to a direction from the first end to the second end.

5. An apparatus according to claim 3 wherein the graft is a saphenous vein.

6. A method for performing a coronary bypass procedure at a coronary vessel disposed lying on an exterior of a heart wall, the method comprising:

securing a first end of a natural vessel graft to a hollow conduit;

inserting the hollow conduit through the heart wall where the conduit and graft define a blood flow path between the first end and a second end of the graft and with the first end in blood flow communication with the heart chamber;

securing the second end to the vessel to direct blood to flow from the blood flow path into the vessel.

7. A method according to claim 6 wherein the coronary vessel is a coronary artery.

8. A method according to claim 6 wherein the conduit is selected to maintain an open blood flow path through the conduit during systole.

9. A method according to claim 6 wherein the first end of the graft is wrapped around an end of the conduit.

10. A method according to claim 6 wherein the graft is selected to have internal valves limiting flow to a direction from the first end to the second end.

11. A method according to claim 10 wherein the graft is a saphenous vein.

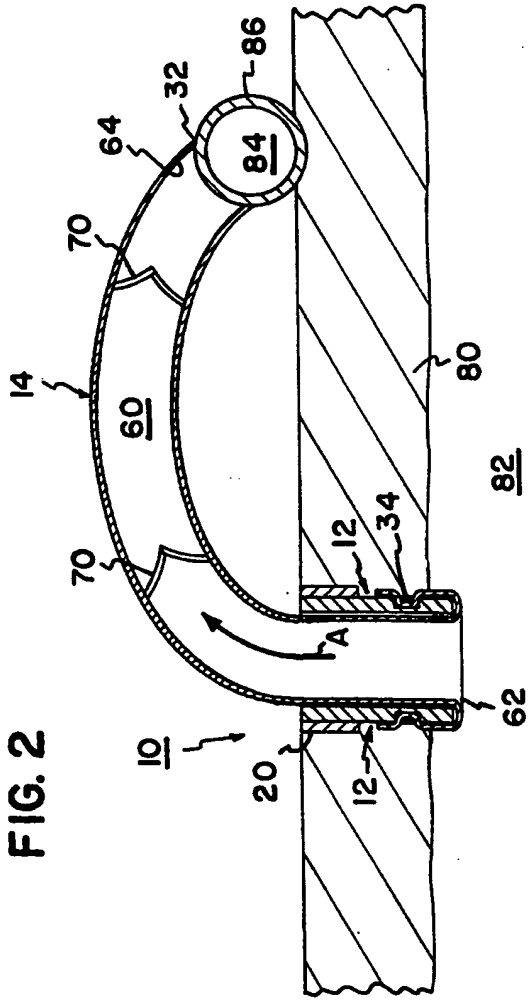
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FIG. 2

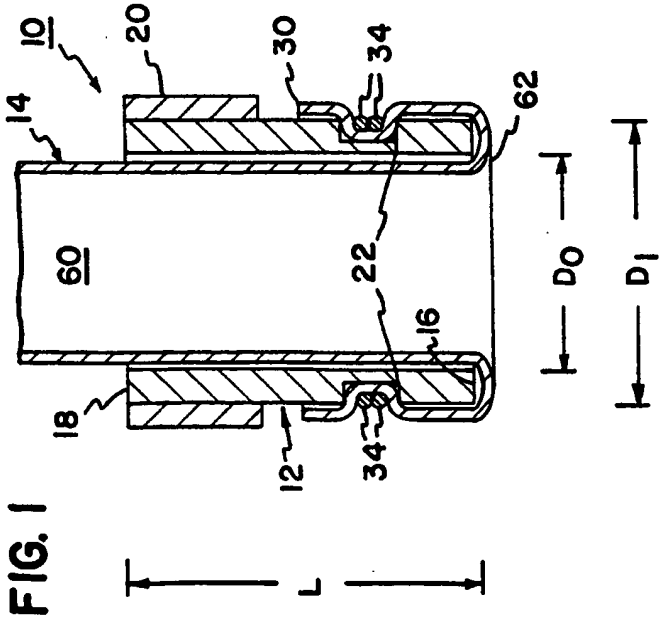
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FIG. 1

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 99/01012

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	MUNRO ET AL: "The possibility of myocardial revascularisation by creation of a left ventriculocoronary artery fistula" JOURNAL OF THORACIC AND CARDIOVASCULAR SURGERY, vol. 58, no. 1, 1 July 1969, pages 25-32, XP002103020 see figure 1 ---	1,2
Y	US 4 769 031 A (MCGOUGH ET AL) 6 September 1988 see column 3, line 42 - column 4, line 2; figures 1,2,4 -----	1,2

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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Date of the actual completion of the international search	Date of mailing of the international search report
18 May 1999	28/05/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

..ternational application No.
PCT/US 99/01012

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 6-11
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ational Application No
PCT/US 99/01012

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4769031 A	06-09-1988	NONE	